

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 7, 1990

Ms. Marcia H. Diamond
Product Manager
Wave Energy Systems, Inc.
218 Little Falls Road
Cedar Grove, NJ 07009

Dear Ms. Diamond,

Thank you for your letter of April 25, 1990, requesting information concerning the use .25% glutaraldehyde disinfectant and the disposal of the medical waste. From the information provided in your letter, it appears that your client wishes to use a 0.25% glutaraldehyde disinfectant to treat crushed sharps contained inside bottles and then dispose of the bottles in a landfill. Your letter requested information regarding the applicability of the Resource Conservation and Recovery Act (RCRA) Subtitle C regulations for hazardous waste management and/or the RCRA Subtitle J medical waste regulations for the management and disposal of these wastes.

Medical waste as defined in 40 CFR 259.10(b) is "solid waste generated in the diagnosis, treatment (e.g. provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals." Regulated medical waste (RMW) is a subset of the total medical waste stream. Sharps, both used and unused, are listed as RMW in Section 259.30(a). Generators of these wastes, who are located in a Covered State (New York, New Jersey, Rhode Island, Connecticut and Puerto Rico), are subject to the requirements of Subpart E and F of Part 259 for medical waste management.

When the glutaraldehyde disinfectant is added to the sharps waste, a waste mixture is created. This waste mixture must first be evaluated to determine if it is a RCRA hazardous waste. If the glutaraldehyde exhibits one of the characteristics of a hazardous waste as outlined in 40 CFR 261 Subpart C (i.e., hazardous waste characteristics are ignitability, corrosivity, reactivity, and toxicity, also see 55 FR 11798, March 29, 1990) then the waste must be managed as a hazardous waste.

If the waste mixture does not exhibit any hazardous waste characteristics, then the waste could be subject to the Part 259 regulations for medical waste management. The Table of Regulated Medical Waste found in Section 259.30(a) includes "sharps" in both Class 4 and Class 7 RMW. Class 4 RMW is defined as "sharps that have been used in animal or human syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents such as used slides and cover slips." Class 7

RMW is defined as “unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.”

RMW which is generated in the Covered States would be subject to the tracking requirements in the Part 259 regulations unless the waste is both “treated and destroyed.” Generators who choose to treat and destroy RMW on-site by a method or other than incineration, are subject to the recordkeeping requirements of Section 259.54(c).

Section 259.10(b) defines treated RMW as “RMW that has been treated to substantially reduce or eliminates its potential for causing disease, but has not yet been destroyed.” While glutaraldehyde has been used in the health care industry as a disinfectant, each generator must determine for his or herself whether the waste has been “treated,” as defined above. The Agency is currently evaluating the effectiveness of patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, various treatment methods, however, generators and RMW treatment facility operators are advised to consult with the waste management agency in their state to determine if additional treatment standards and requirements apply. (See 54 FR 12343, March 24, 1989.)

Section 259.10(b) also defines destroyed RMW as “RMW that has been ruined, torn apart, or mutilated through process such as thermal treatment, melting, shredding, grinding, tearing or breaking, so that it is no longer generally recognizable as a medical waste. It does not mean compaction.” The intent of this requirement was to subject the waste to processes which physically change the RMW, rendering the waste stream unrecognizable. Clearly, a crushing process would not be an adequate method of destroying most types of sharps.

Thus, if RMW is not treated and destroyed it must be tracked from point of generation to disposal. The Part 259 regulations contain recordkeeping requirements for disposal facilities, such as landfills, which accept RMW. Additionally, state and the federal requirements under RCRA Subtitle D, regulations for municipal solid waste management would also apply. Therefore, your client should contact the appropriate state agency to determine what state regulations are applicable to the disposal of this specific waste stream.

I have enclosed a copy of the Medical Waste Tracking Act and the Part 259 Standards for the Tracking and Management of Medical Waste for your convenience. If you have any further questions or need additional information please contact the RCRA/Superfund Hotline at (800) 424-9346 or Mary Greene at (202) 475-8551.

Sincerely,

David Bussard, Director
Characterization and Assessment Division

FaxBack # 11558